

ORIGINAL

TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

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COMMENTS:

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Via Certified Mail

March 9, 2012

TSCA Confidential Business Information Center (7407M)
EPA East – Room 6428
Attn: Section 8(e)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001



Re: TSCA Section 8(e) Notification of Substantial Risk: 3-(triethoxysilyl)propanethiol (CAS 14814-09-6)

Dear TSCA Section 8(e) Coordinator:

In accordance with the provisions of Section 8(e) of the Toxic Substances and Control Act (TSCA), as interpreted in the TSCA Section 8(e) Policy Statement and Guidance, Fed. Reg. 33129 (June 3, 2003) and other Agency guidance, the Silicones Environmental, Health and Safety Council (SEHSC)¹ submits, on behalf of its member companies, information concerning a study with 3-(triethoxysilyl)propanethiol (CAS 14814-09-6). Neither SEHSC, nor any member company, has made a determination at this time that any significant risk of injury to human health or the environment is presented by these findings

Chemical Substances

3-(Triethoxysilyl)propanethiol (CAS 14814-09-6)

Study Title

In Vitro Mammalian Gene Cell Mutation Assay Thymidine Kinase Locus (TK +/-) in Mouse Lymphoma L5178Y cells with 3-(Triethoxysilyl)propanethiol.

Summary



¹ SEHSC is a not-for-profit trade association whose mission is to promote the safe use of silicones through product stewardship and environmental, health, and safety research. The Council is comprised of North American silicone chemical producers and importers.

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Results from an *in vitro* mammalian gene cell mutation assay conducted with 3-(triethoxysilyl)propanethiol (CAS 14814-09-6; the test substance) indicate the test substance is mutagenic without metabolic activation. A clastogenic effect was noted.

Details

Study Design

In an OECD test guideline 476 study, the test substance was investigated at the following concentrations:

	Concentration tested (mM)	
	With metabolic activation	Without metabolic activation
Experiment I (4-hour)	0.05, 0.10, 0.20, 0.30, 0.40, 0.50, 0.60, 0.70	0.01, 0.02, 0.05, 0.10, 0.20, 0.30, 0.40, 0.48, 0.56
Experiments II (24-hour)	0.12, 0.25, 0.35, 0.52, 0.58, 0.64, 0.68, 0.72	0.04, 0.08, 0.10, 0.15, 0.20, 0.25, 0.30, 0.35

Results

Precipitation was noted in Experiment I without metabolic activation at ≥ 0.48 mM. Growth inhibition was noted in both experiments at all conditions. Positive control substances provided positive responses as expected, indicating the test was valid and sensitive.

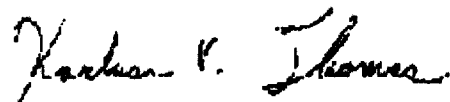
In Experiment II without metabolic activation the Global Evaluation factor (GEF; defined as the mean of the negative/vehicle mutation frequency plus one standard deviation) was exceeded by the induced mutant frequency in two concentrations (0.20 and 0.25 mM), but not at the two highest dose levels. A slight dose-response relationship was observed in Experiment I without metabolic activation. In Experiment II without metabolic activation an increase in small colonies was noted combined with mutagenicity.

Action

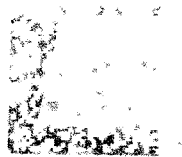
A copy of the final report for this study is attached.

If you have any questions concerning this submission, please contact me at (703) 788-6570, kthomas@sehsc.com, or at the address provided herein.

Sincerely,



Karluss Thomas
Executive Director



CERTIFIED MAIL



7001 0360 0002 3429 7266



Silicones Environmental, Health and Safety Council
of North America

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